K111029

JUL - 6 2011

Section 8.

510(k) Summary

1. Submitter Information

Company name	TaiDoc Technology Corporation
Contact person	Teling Hsu
Address	3F, 5F, No. 127, Wugong 2nd Rd., Wugu Township, Taipei County, 248, Taiwan
Phone	(886-2) 6625-8188 #1176
FAX	(886-2) 6625-0288
E-mail	teling.hsu@taidoc.com.tw
Date Prepared	April 12, 2011

2. Name of Device

Trade Names	FORA POCT Management System
Common Names	Diabetes Data Management Software Program
Classification	Class II Device (21 CFR 862.1345) Class I Device (21 CFR 862.2100)
Product Code	NBW, JQP

3. Predicate Device

Trade/Proprietary Name:	AtLast® Data Management Software (DMS)
Common/Usual Name:	Diabetes Data Management software Program
Submitter	Amira Medical
510 (k) Number	K010605

4. Device Description

The FORA POCT Management System is designed for using in hospital or health institute environment. The system provides management on quality control data, Blood Glucose Measurement, Stock Control, Meter Setting, Operator and Operation Units with multiple reporting options and tools.

The information uploaded from meters is arranged and analyzed by graphs and summarizes tables according to various groups of functions. It allows the

user to make management and improvement decisions more effectively.
Through evaluation of the historical test results, healthcare professionals can do health management effectively.

5. Intended Use

The FORA POCT Management System is data management software.
Patient historical data transmitted is able to be reviewed and analyzed in this system.

The FORA POCT Management System may not be used as a substitute for direct medical intervention. Interpretation of the information collected and transmitted requires clinical judgment by an appropriate healthcare professional.

6. Comparison to Predicate Device

The FORA POCT Management System is substantially equivalent to the AtLast® Data Management Software (K010605).

7. Performance Studies

Testing of FORA POCT Management System indicates that the system meets the acceptable criteria.

8. Conclusion

FORA POCT Management System demonstrates satisfactory performance and is suitable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

JUL 0 6 2011

Taidoc Technology Corporation
c/o Teling Hsu
Regulatory Affairs Specialist
3f,5f, No.127 Wugong 2nd Rd., Wugu Township
Taipei County, 24888
TW - CHINA (TAIWAN)

Re: k111029
Trade/Device Name: FORA POCT Management System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system.
Regulatory Class: II
Product Code: NBW, JQP
Dated: April 12, 2011
Received: April 13, 2011

Dear: Ms. Hsu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Section 7.

Indications for Use

510(k) Number: K111029

Device Name: FORA POCT Management System

Indications for Use:

The FORA POCT Management System is a data management software and designed for using in hospital or health institute environment. Patient historical data transmitted is able to be reviewed and analyzed in this system.

The FORA POCT Management System may not be used as a substitute for direct medical intervention or emergency care. Interpretation of the information collected and transmitted requires clinical judgment by an appropriate healthcare professional.

Prescription Use X And/Or Over the Counter Use _____

(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K111029